REMARKS

Claims 20-27 are pending in this application. Claims 23, 26 and 27 are amended herein. No new matter is added. Reconsideration of the claims in view of the foregoing amendments and following comments is respectfully requested.

Rejection of Claims 20 and 23 Under 35 U.S.C.§ 112, first paragraph

The examiner rejected claims 20 and 23 under 35 U.S.C. §112, first paragraph. In paragraph 5 of the office action, the examiner asserted that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with the claims. The examiner asserted that the specification does not reasonably provide enablement for a device having a construction that completely blocks air flow through the bronchial passageway.

Applicants respectfully disagree. As described below, the specification provides enablement for a device having a construction that completely blocks air flow through the bronchial passageway. The specification contains sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention without undue experimentation. In addition, the specification provides sufficient written description of the claims. The specification describes the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.

The specification describes a flow device having a valve body 24 and a resilient seal 20 that includes polymeric material capable of sealing within the interior of the body passageway. When the device is placed in a bronchial passageway, the seal 20 defines a peripheral seal with the interior wall of the passageway. At one end of the seal 20, a valve support 22 extends inwardly from an attachment to the valve body. This valve support 22 provides a barrier to flow through the resilient seal. (See Specification page 4, lines 2-13; page 5, lines 15-17.) In addition, as acknowledged by

the examiner, no flow can occur across the valve when the valve body is closed. (See Specification, page 4, lines 20-22.)

As shown in Figure 1, the elastomeric material of the seal 20 can extend around the entire periphery of the flow control device. The seal 20 can have a circular cross-section and a bronchial passageway also has a circular cross-section. Thus, when the flow control device is implanted in a bronchial passageway, the seal 20 makes continuous sealing contact with the interior wall of the passageway around the entire periphery of the flow control device. Accordingly, fluid must flow through valve body 24 in order to flow across the flow control device through the bronchial passageway. When the valve body is closed, the flow control device would necessarily completely block fluid flow through the bronchial passageway, as the sealing contact between seal 20 and the bronchial wall would prevent fluid from flowing between the seal 20 and the interior wall of the bronchial passageway. The flow control device has no suture holes or attachment seams through which air might flow, as the valve body 24, valve support 22, and seal 24 can all be formed of a single piece of flow-blocking material. Any flow that occurs across the device in its entirety must be through the valve body, as there is no other passageway in the device through which air can flow. Thus, when the valve is closed, the device in its entirety completely blocks air flow through the bronchial passage. Accordingly, the specification provides enablement for a device having a construction that completely blocks fluid flow through the bronchial passageway.

The examiner asserted that the specification does not limit the inwardly extending disks 38 and 40 as completely blocking air if the device was implanted in a bronchial passageway. Applicants respectfully disagree. The specification states that the valve support 22 provides a barrier to flow through the resilient seal. (See Specification page 4, lines 11-13). The disk elements 38 and 40 are both part of the valve support 22 (see Specification, page 6, lines 9-16) and, therefore, also provide a barrier to flow through the resilient seal. Moreover, the valve body 24, valve support 22, and disk elements 38 and 40 can be formed as one piece of the same material. (See Specification, page 4, lines 15-16; Figs 2-3.) The examiner acknowledged that the specification is enabling for a device having a construction such that no air flow occurs

across the valve body. If no air flow occurs across the valve body, then no flow would occur across the valve support and the disk elements, which are made of the same material as the valve body and which have no openings for air to flow through.

Applicant notes that the specification need not use the exact same terms as the claims in order for the disclosure to satisfy the written description requirement of 35 U.S.C. §112. By disclosing a device that inherently has a property, a patent application necessarily discloses that property, even though the application may say nothing explicit concerning it. In the instant case, specification states that no flow can occur through the closed valve body and further states that the valve body, seal, and valve support can all be formed of the same flow-blocking material. Because any flow across the device must occur through the valve body, the application describes a flow control device having a construction that would necessarily completely block air flow through a bronchial passageway when the valve is in the closed configuration.

As further support that the specification provides enablement and adequate written description for a device having a construction that completely blocks air flow through a bronchial passageway, Applicants submits herewith the Declaration of Antony Fields.

In view of the foregoing, Applicants respectfully submit that the rejection under 35 U.S.C.§ 112, first paragraph, should be withdrawn.

Rejection of Claims 20 and 23 Under 35 U.S.C.§ 112, second paragraph

The examiner rejected claims 23-25 and 27 under 35 U.S.C. §112, second paragraph. The examiner asserted that there is insufficient antecedent basis for the terms "the device" and "the flow control device" in the claims. Claims 23 and 25 have been amended to provide antecedent basis for these terms. Applicants submit that the rejection under 35 U.S.C.§ 112, second paragraph, has been overcome.

Rejection of Claims 26 & 27 Under 35 U.S.C. § 103(a)

The Examiner rejected claims 20-25 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Alferness (USPN 6,293,951) in view of Shaw (WO 01/87170 A1).

Alferness has a filing date of August 29, 1999, which is after the priority date of September 16, 1997 of the instant application. However, the examiner asserts that the effective filing date of claims 20-25 is February 21, 2002 based on the examiner's allegation of lack of enablement of these claims. As discussed above, applicants assert that the specification provides enabling support for claims 20-25. Therefore, claims 20-25 have an effective filing date of September 16, 1997. Accordingly, it is respectfully submitted that Alferness is not effective as prior art against the instant application. Applicants respectfully request that the rejection of claims 20-25 under 35 U.S.C. § 103(a) be withdrawn.

Rejection of Claims 20-25 Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 26 and 27 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Andersen (USPN 5,411,552) in view of Moasser (USPN 4,417,360). Claims 26 and 27 have been amended to recite that the valve has a construction such that no air flow occurs through the flow control device and through the bronchial passageway when the valve is in the closed configuration. As discussed above, the specification provides support for such a claim.

The Andersen valve has a construction that would permit some air to flow through the device even when the valve is closed. The Andersen device uses a stent that is formed by a pair of folded wire rings that are sutured to one another. ("The two rings are placed on top of each other as will appear from FIG. 1 and they are mutually secured by means of a number of sutures (not shown)." See Col. 5, lines 19-22.) Such sutures create holes and other imperfections that form leak paths for air to flow across and through the device even when the valve is closed. Thus, although the valve itself might be attached to the stent by gluing or welding, the device would still have suture holes at the attachment of the folded wire rings that form the stent. The Andersen device therefore does not have a construction such that no air flow occurs through the device.

Moasser describes a prosthetic valve that includes a tube 16 and a pair of flaps 18 and 20 that are formed of fabric. Because a fabric is a woven material, the weaves

in the tube and the flaps would form leak paths through which air can flow through the device even when the valve is closed.

Consequently, applicants respectfully submit that the rejection of claims 26-27 under 35 U.S.C. § 103(a) should be withdrawn.

Conclusion

It is believed that all of the pending claims have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to it amendment.

In view of the above amendments and remarks, all of the claims should be in condition for allowance. A formal notice to that effect is respectfully solicited.

Respectfully submitted,

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